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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of
Ibrahim, et al.

Group Art Unit: 1655

Serial No.: 09/444,095

Examiner: Sisson, B.

Filed: November 22, 1999

FOR: Purification Method and Apparatus

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AMENDMENT

Hon. Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Responsive to the Office Action dated December 11, 2002, please amend the claims as follows and consider the following remarks:

IN THE CLAIMS:

Please amend the claims as follows:

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68. (Amended) The method of claim 63, wherein said DNA coating is single stranded DNA and double stranded hybridization structures are formed.

69. (Amended) The method of claim 63, wherein said DNA coating is double stranded DNA and triplex hybridization structures are formed.

REMARKS

Claims 31-35, 38, 39, 63 and 65-70 are pending in the application. Claims 68 and 69 have been amended to correct dependency in response to the Examiner's objection that they were dependent on a cancelled claim. This amendment should overcome the Examiner's objection under 37 CFR 1.75(c) and rejection under 35 USC §112, second paragraph.

Claims 31-35, 38, 39, 63 and 65-67 have been rejected under 35 USC 103(a) as allegedly unpatentable over Boom et al. in view of Impraim et al and Schnipelsky et al. Applicants respectfully traverse this rejection.

The present claims under examination are directed to a purification method for recovering purified DNA or RNA from a sample using an assembly as claimed that requires a wand having a cap, a shaft and a sample collection assembly with microstrutures. The claims also call for reservoir tubes that are securely and sealingly closed by the cap on the wand. The purpose for this unique design is at least two fold and solve two problems at once. First the microstructures are present to increase the surface area of the sample collection assembly to capture a greater amount of nucleic acids. Secondly, the use of the wand and reservoir tubes permits a military service member or other user to perform nucleic acid purification of a sample out in the field, for example during a military action where there is no electricity to vortex a sample. A user can simply agitate the reservoir tubes with the wand/sample collection assembly in place to cause the desired reaction to occur.

Bringing the answer to these to these two problems into a single apparatus and method has not been discloses or suggested by any of the cited references.

Boom, et al. is directed to a method for the purification of nucleic acids. Boom et al. discloses the use of silica particles to capture nucleic acids. However, the silica particles are free floating in solution and are not attached to a "sample collection assembly" on a wand. Further, Boom et al. does not suggest any need to attach the silica particles to a "sample collection assembly" on a wand. Thus, Boom et al. does not render obvious the presently claimed invention that requires "*said wand comprises a cap, a sample collection assembly and an elongated shaft connecting said cap to said sample*

collection assembly, said sample collection assembly having microstructures for increasing the surface area of the sample collection assembly." Boom et al. does not solve the problems that the present invention is designed to solve as stated above.

Impraim et al. is directed to a non radioactive hybridization assay and kit. The Examiner has cited this reference for its teaching at column 7 of the use of beads, dipsticks, microparticles as solid supports. Impraim et al. does not however, disclose the use of beads or microparticles bound to a solid support such as a wand. Rather, Impraim et al. discloses many solid supports, but no wand with a sample collection assembly with microstructures.

All the solid supports disclosed in Impraim et al. have smooth surfaces. Test tubes that are directly coated with anti-hybrid antibody are preferred in this reference. There is no mention of any method wherein a reservoir tube is used in combination with a wand with microstructures or any suggestion for a need for a device that could be used without electricity. In fact, the method in Impraim et al. uses an electricity run platform shaker with shaking speeds of up to 1500 rpm in its method. The device in Impraim et al. would not be useful for the same purpose that the presently claimed invention is useful for and does not solve the problem of purification of nucleic acids in the field where no electricity exists.

Further, Impraim et al. does not suggest taking silica particles and attaching them to a solid surface. The only thing that is attached to a solid surface in Impraim et al. is anti-hybrid antibody. Hence, one of ordinary skill in the art does not have the required motivation from this reference to modify Boom et al. to arrive at the present invention.

Schnipelsky et al. is directed to a containment cuvette for PCR and method of use. The Examiner cited this reference to show the use of immobilized beads. However, the device in Schnipelsky et al. is much more complex than the device used in the claimed method. It is a cuvette that has a means for controlling temperature for cycling the contents of the reaction compartment through a temperature range of 30° to 95° C, a means for providing liquid interconnection between compartments by pressurizing the liquid, a detection material capable of generating a detectable signal, etc. The device in

Schnipelsky et al. could not be used without electricity as could the claimed invention. The immobilized beads are not present on a sample collection assembly of a wand. There is simply no teaching of why one of ordinary skill in the art would be motivated to take the beads and put them on a wand. There is no apparent need in Schnipelsky to immobilize the beads on a wand. Hence, this reference doesn't make up for the deficiencies of the other references.

None of the cited references, whether taken alone or in combination would have lead one of ordinary skill in the art to the present invention because none of them teach or suggest the use of microstructures on a wand, the use of reservoir tubes that are sealed by the cap of a wand or any need to have such a device. Hence, the rejection under 35 U.S.C. §103(a) is believed overcome.

Reconsideration and allowance are respectfully requested. The Examiner is invited to telephone Applicant's representative at (301) 924-9500 if it would in any way expedite prosecution.

Respectfully submitted,

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